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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/658,736      | 09/11/2000  | James M. Zavislan    | ML-0414DIV          | 3878             |

7590 04/28/2004

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| EXAMINER |
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SMITH, RUTH S

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| ART UNIT | PAPER NUMBER |
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3737

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/658,736

Applicant(s)

ZAVISLAN, JAMES M.

Examiner

Ruth S Smith

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-8, 19-23, 26-37 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5 and 7 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6, 8, 19-20, 23, 26-37, 42-46 is/are rejected.
- 7) ☒ Claim(s) 21 and 22 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Double Patenting***

The terminal disclaimer filed March 23, 2004 has overcome the double patenting rejection set forth in the previous office action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,8,19,26-37,42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Dhawan. The claims are directly readable on Dhawan which discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Placement of the platen with respect to the tissue to be imaged inherently includes the means for moving it into position as set forth in claim 2. The imaging head is capable of imaging a section of tissue from light returned from focused light under the surface of the tissue as seen in figure 3. The imaging means is capable of imaging sections through different planes given the volume of tissue imaged.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3,20,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dhawan in view of Jester et al, "In Vivo, Real-time Confocal Imaging". Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Jester et al disclose means for fixing the position of the imaging device with respect to an area of the patient before it is lowered into place on the patient. It would have been obvious to one skilled in the art to have modified Dhawan such that it includes means for temporarily fixing the imaging with respect to the patient before it is moved into contact with the tissue. Such a modification allows for more precise positioning and handling of the device. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head would have been an obvious design choice to one skilled in the art.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dhawan. Dhawan discloses a system for examining tissue by maintaining the tissue under stress and examining the tissue under stress with a confocal imaging camera. The means for maintaining the tissue under stress includes a platen 54 and suction means which applies a force against at least the edges of the area of skin tissue being imaged. The opening in the platen 54 includes a material window as part of element 44. Dhawan discloses means for moving the imaging head with respect to the orifice in that the camera can be inserted into the device. In the absence of any showing of unexpected results, the means used to move the head would have been an obvious design choice to one skilled in the art.

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### ***Allowable Subject Matter***

Claims 4,5,7 are allowable over the prior art of record.

Claims 21-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Response to Arguments***

Applicant's arguments filed March 23, 2004 have been fully considered but they are not persuasive. The imaging head is capable of imaging a section of tissue from light returned from focused light under the surface of the tissue as seen in figure 3. With regard to the rejection of claims 3,20,23, the applicant's arguments are noted, however, the examiner does not agree and still finds the combination of references to be obvious to one skilled in the art. Applicant's argument regarding claim 6 do not appear to be directed to the claimed limitation. It appears that applicant is interpreting the claim language too narrowly.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith  
Primary Examiner  
Art Unit 3737

RSS